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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,140	06/06/2001	Markus Eickmann	058315/0127	6537
26633	7590	10/04/2005	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			SALIMI, ALI REZA	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/874,140	Applicant(s) EICKMANN ET AL.	
	Examiner A R. Salimi	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-22 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14 and 17-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of: -
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/219,337.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

✓

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II (Claims 15, and 16) in the reply filed on 9/14/2005 is acknowledged. The traversal is on the ground(s) that the search for other groups is not burdensome. This is not found persuasive because the separate classification of the subject matter is a prima facie showing of burden, which is not overcome by Applicants' assertion to the contrary.

The requirement is still deemed proper and is therefore made FINAL.

Applicants are reminded to cancel the claims to the non elected Group(s).

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the earlier filed application(s) in the first sentence of the specification (37 CFR 1.78). Please, up-date the information by inserting the patent number.

Claim Rejections - 35 USC § 112

Claims 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is vague and indefinite, the metes and bounds of the intended sequences that are “homologous” to the VP26 region are not defined. The claim has been interpreted in view of the specification and it not clear what sequences are encompassed as homologous or identical. Identity, homology or sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. Applicant has referred to homologous, but there is no indication of the utilized algorithm to calculate the sequence identity. Still further, In addition, “homology” is attributed to sequences which share a common evolutionary history. In other words, if there existed an ancestral molecule in the past that was ancestral to the sequences. The claims do not set forth any sequences having common evolutionary history. In addition, a sequence identification number should identify the intended amino acid region of AA 12 to 235. This affects the dependent claim 16.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. In the instant case Applicants have only disclosed AA 12 to 235 of VZV VP26 to be utilized in a diagnostic assay and react with serum antibodies only and

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do not provide any guidance for homology sequences. The specification is silent as to the criteria used to obtain variables homologous to the selected amino acids region. In addition, there is no evidence or support in the specification indicating that the multiple homologous variations would render the positive immunoreactive response, and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed regions. Therefore, a written description of the other claimed sequences should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 19 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-

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encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

and at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Davison et al (J. of General Virology, 1992).

The polypeptide disclosed by the above cited art meets the broad limitations of the claimed invention. The polypeptide disclosed is homologous to the claimed region and meets the limitations of the claims. Applicants are reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art

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products. In addition, Applicants are reminded that the intended use of a product disclosed in the prior art does not hold patentable weight.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al (US Patent No. 4,686,101).

The polypeptide disclosed by the above cited art patent meets the broad limitations of the claimed invention. The polypeptide disclosed is homologous to the claimed region and meets the limitations of the claims. Applicants are reminded that claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Still further the intended use of a product disclosed in the prior art does not hold patentable weight.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Davison et al (J. of General Virology, 1986, Vol. 67, pages 1759-1816).

The claimed product is clearly anticipated by the above cited art. Davison et al taught a product of gene 23 as a 235 amino acids long polypeptide, which is VP26 (see page 1776, and page 1810). In addition, Applicants are reminded that the intended use of a product disclosed in the prior art does not hold patentable weight. Thus, the 235 amino acids long protein taught by the above cited anticipates the now claimed invention

No claims are allowed.

Conclusion

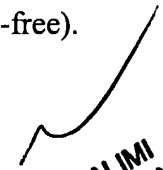
Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi
9/30/2005


ALI R. SALIMI
PRIMARY EXAMINER